NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HOWMEDICA OSTEONICS CORP.,	:	
Plaintiff,	:	**OPINION**
v.	:	Civ. No. 05-897 (WHW)
ZIMMER, INC., CENTERPULSE ORTHOPEDICS, INC., (formerly known as SULZER ORTHOPEDICS, INC.) and SMITH & NEPHEW, INC.,	:	
Defendants.	:	

Walls, Senior District Judge

In this action brought by Howmedica Osteonics Corp. ("Howmedica") for infringement of four of its patents relating to medical implants, defendants Zimmer, Inc., Zimmer Austin, Inc., and Smith & Nephew, Inc. move jointly for summary judgment on the issues of invalidity and non-infringement as to three of those patents. Defendants' motion for summary judgment on invalidity asks the Court to determine that numerous patent claims are invalid because they contain an equation term ("Arrhenius' equation") which is not amenable to definite construction by a person of ordinary skill in the art. Defendants' motion for summary judgment on non-infringement principally argues that Howmedica is foreclosed from proving infringement because it has not disclosed in discovery the precise manner in which defendants' products

infringe its patents.

Having considered the parties' written submissions and oral arguments, the Court grants defendants' motion for summary judgment on invalidity. Accordingly, it will not address the motion for summary judgment on non-infringement.

FACTS AND PROCEDURAL HISTORY

A. Parties and Procedural History

Howmedica is a New Jersey corporation that manufactures and markets medical implants such as artificial knee and hip implants. Starting in 1993, Howmedica filed a series of related patents that disclose processes for irradiating and then heating polymers used in medical implants. The treatment increases the oxidation resistance of the polymer. A polymer with greater oxidation resistance retains its physical properties better, which makes it more suitable for use in medical implants because it deteriorates more slowly in the body.

Defendants Zimmer, Inc., Zimmer Austin, Inc., and Smith & Nephew, Inc. are also corporations in the business of manufacturing and marketing medical implants. In February 2005, Howmedica filed suit against defendants, alleging that they had violated 35 U.S.C. § 271 by infringing four of Howmedica's patents relating to polymeric materials used in medical implants. These four patents are U.S. Patent No. 6,174,934 B1 (filed Jan. 23, 1998) ("the '934 Patent"); U.S. Patent No. 6,372,814 B1 (filed June 28, 2000) ("the '814 Patent"); U.S. Patent No. 6,664,308 B2 (filed Jan. 8, 2002) ("the '308 Patent"); U.S. Patent No. 6,818,020 B2 (filed June 13, 2003) ("the '020 Patent") (collectively, "the patents-in-suit"). Howmedica claims that four of

the defendants' products, Longevity, Prolong, Durusul, and XLPE, infringe on these patents.

In January 2006, after considerable discovery, the parties filed reciprocal Markman motions requesting that the Court construct numerous patent claims. On July 27, 2006, defendants filed the present motion for summary judgment. The Court decided the Markman motions in April 2007. The parties argued the motion for summary judgment on May 15, 2006.

Defendants move for summary judgment on the issues of noninfringement and the invalidity of the asserted claims of Howmedica's '934, '814, and '308 Patents. They argue that they are entitled to summary judgment on invalidity because the Howmedica patent claims at issue do not provide precise boundaries to the inventions they disclose. Defendants also seek summary judgment on non-infringement because Howmedica is unable to demonstrate how defendants' products infringe on these three patents. As said, the Court will not reach the issue of non-infringement because it finds the patents invalid.

B. The Invention

1. Background

Howmedica's patents describe a process for making medical implants from a polymer, typically ultra-high molecular weight polyethylene ("UHMWPE"), that has been irradiated and then heated. Irradiating and then heating the polymer in an oxygen-free environment for a defined period of time at a defined temperature will cause chemical reactions that make the polymer stronger by forming cross-links between polymer chains.

The initial irradiation of the polymer causes chemical bonds between sections of the polymer molecule to undergo scission (to split). Scission creates free radicals, or atoms and

molecules which have unpaired electrons in their outermost electron shell. Free radicals are highly reactive because unpaired electrons in the outermost shell allow an atom or molecule to form bonds more easily by sharing those electrons with other atoms or molecules.

The free radicals created by irradiating a polymer will react in two different ways. First, they will cause post-irradiation degradation of the polymer, i.e., further scission. Second, they will bond to one another and become inert. This latter process is called cross-linking. If the polymer is irradiated while exposed to oxygen, the free radicals will cause a significant amount of post-irradiation degradation of the polymer in comparison to the amount of cross linking. In contrast, if the polymer is irradiated in an inert atmosphere, more cross-linking and less post-irradiation degradation will occur. When the ratio of chain scission reactions to cross-linking reactions is lower, the polymer retains its qualities better over time. In other words, irradiating the polymer in an inert atmosphere creates a stronger material than irradiating it in oxygen.

2. Howmedica's Improvement on Prior Art

Howmedica cites two principal types of prior art in its patents. First, Howmedica cites patents that disclose irradiation of polymers (in the form of medical devices and otherwise) out of contact with oxygen to prevent post-irradiation oxidation. Second, Howmedica cites patents that describe heating processes which improve the physical characteristics of ultra-high molecular weight polyethylene.

Howmedica's patent avowedly improves on prior art by disclosing a process whereby the polymer is irradiated and then heated for such a period of time that allows for a desired level of free radical cross-linking to occur. Both steps, irradiation and heating, take place out of contact

NOT FOR PUBLICATION

with oxygen. Heating the polymer "helps free radicals . . . to migrate in the plastic matrix to meet other neighboring free radicals for cross-linking reactions." '934 Patent, 5:53-55. The patent specifications state that the post irradiation heating step has to be of a sufficient duration and temperature to reduce the number of free radicals "to a minimal or an accepted level." '934 Patent, 7:05-07.

3. Arrhenius' Equation

The '934, '814, and '308 Patent claims at issue in the motion for summary judgment all define the range of sufficient heating time and temperature combinations by referring to Arrhenius' equation. These claims state that the implant material is heated at a temperature and for a time at least equivalent to 50°C for 144 hours under Arrhenius' equation. Claim 23 of the '934 Patent is representative of these claims:

> A medical implant comprising an ultra-high molecular weight polyethylene material . . . , said material irradiated to create free radicals in the absence of a free radical generation catalyst while out of contact with oxygen . . . and then **heated** while out of contact with oxygen . . . **at a temperature of greater than 25°C for a sufficient time to create a level of cross-links between free radicals wherein the temperature and time are selected to be at least equivalent to heating said irradiated material at 50°C for 144 hours as defined by the Arrhennius' equation (14)**.

'934 Patent, claim 23 (emphasis added).[1] In general, a chemical reaction will progress more quickly at a higher temperature, and more slowly at a lower temperature. Arrhenius' equation quantifies the relationship between the temperature at which a particular reaction occurs and the

[1]The following claims are at issue in this motion for summary judgment: claims 23, 27, 29, 50, and 52 of the '934 Patent; claims 7, 12, and 19 of the '814 Patent; and claims 1, 5, 10, 12, 16, 21, 23, and 24 of the '308 Patent. All of these claims either incorporate the Arhennius' equation term, or are dependent from claims that incorporate that term.

NOT FOR PUBLICATION

rate at which it proceeds. In the case of the invention described in Howmedica's claims, Arrhenius' equation is used to define the time and temperature required to achieve a particular amount of interlinking between free radicals in an irradiated polymer. This amount of interlinking is associated with a desirable level of oxidation resistance, resistance to solvents, durability, etc., for medical implants.

The section of each patent's specification which discusses the preferred embodiment sets forth Arrhenius' equation. The '934 Patent specification is representative:

> In general, if a higher temperature is used, a shorter time period is required to achieve a prescribed level of oxidation resistance and cross-linking. In many cases, the relationship between the reaction temperature and the reaction rate follows the well-known Arrhennius [sic] equation:
>
> k_1 or $k_2 = A*\exp(-\blacktriangle H/T)$ (14)
>
> where
>
> k_1 and k_2 are reaction rate constants from reactions 13
> A is a reaction dependent constant
> ▲H is activation energy of reaction
> T is absolute temperature (K)

934 Patent, 6:53-65. "Reactions 13," which are the source of the k_1 and k_2 terms in Arrhenius' equation in the specification, are also defined in the specification:

> [T]he rate of free radical reactions . . . increases with increasing temperature, according to the following general expressions:
>
> $$\frac{dr\cdot}{dt} = k_1[r\cdot] \quad \text{and} \quad \frac{dP\cdot}{dt} = k_2[P\cdot] \qquad (13)$$
>
> Compared to room temperature, an elevated temperature not only increases the reaction rate constants, k_1 and k_2, but also helps free radicals r· and P· to migrate in the plastic matrix to meet other neighboring free radicals for cross-linking reactions.

'934 Patent, 5:43-55. Howmedica defines the terms r· and P· in the specification as "primary free

NOT FOR PUBLICATION

radicals r·" and "secondary free radicals P·," both of which are produced through a series of reactions when a polymer is irradiated. '934 Patent, 2:56-57. Otherwise the terms of the "reactions 13" are not defined by the specification.

In its opposition to the motion to dismiss, Howmedica revises the equation set forth in the patents' specifications. Instead of defining Arrhenius' equation as it had initially, as equation 14 in the patent specifications, '934 Patent, 6:58, Howmedica now defines Arrhenius equation as:

k_1 or $k_2 = A*\exp(-\blacktriangle H/R*T)$ [2]

(Howmedica Opp'n at 11.) It explains the omission of "the gas constant R" from the specification as an "uncorrected typographical error."[3] Id.

---

[2]Dr. Stephen Li, in his expert declarations, represents the relationship of the Arrhenius' equation terms more clearly than the specification:

$$k = A*\exp\left[\frac{-\blacktriangle H}{R*T}\right]$$

(Decl. of Dr. Stephen Li, Aug. 24, 2006, ¶ 20.)

[3]Howmedica states that the omission of the "gas constant 'R'" from the specification is of no consequence, since "[o]ne of the ordinary skill in the art understands that the Arrhennius [sic] equation includes the gas constant 'R'" as set forth in the revised equation. (Howmedica Opp'n at 11.) Howmedica supports this assertion with expert declarations and other evidence. (See Li Decl. ¶ 21; Decl. of William M. Risen, Jr., Aug. 24, 2006, Ex. 1 at 556.) Since defendants do not challenge Howmedica's assertion, the Court finds a person of ordinary skill in the art would understand the Arrhenius equation in the specification as containing a typographical error because the equation must include the "gas constant 'R.'" The Court construes the equation referenced in the claim to contain the gas constant. See ISCO Int'l, Inc. v. Conductus, Inc., No. 01-587, 2003 WL 276250, at *5 (D. Del. Feb. 10, 2003) (disregarding typographical error clear to one skilled in art when construing claim); Baily v. Dart Container Corp. of Michigan, 157 F. Supp. 2d 110, 124 n.7 (D. Mass. 2001) (same).

NOT FOR PUBLICATION

C. The Dispute

Defendants argue that Howmedica's patent claims are invalid because they are indefinite. They maintain that it is impossible for a person of ordinary skill in the art to apply the Arrhenius' equation term in the patent claims and so define the boundaries of the patent claims. Howmedica argues that the information contained in the specification is adequate for a person of ordinary skill in the art to derive the various Arrhenius' equation terms and determine whether her product infringes on Howmedica's.

LEGAL STANDARD

Defendants seek summary judgment on the ground that the asserted claims of '934, '814, and '308 Patents are invalid because they are indefinite. Summary judgment is appropriate when the moving party establishes that "there is no genuine issue as to any material fact and that [it] is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). Whether a particular patent is "invalid for indefiniteness presents a question of law," Exxon Research and Engineering Co. v. United States, 265 F.3d 1371, 1376 (Fed. Cir. 2001), because "claim indefiniteness is a legal conclusion that is drawn from the court's performance of its duty as the construer of patent claims." Personalized Media Comm'ns, L.L.C. v. Int'l Trade Comm'n, 161 F.3d 696, 705 (Fed. Cir. 1998). Indefiniteness remains a matter of law, and the proper province of the court, even when the determination of claim's indefiniteness depends on an underlying issue of fact. Exxon, 365 F.3d at 1376. In such circumstances the court will consider those underlying factual issues and rule on indefiniteness as a "matter of law on summary judgment." Id.

NOT FOR PUBLICATION

35 U.S.C. § 112 outlines the requirements for patent specifications and claims. That section states that for a patent claim to be valid, it must be definite:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The statute requires definiteness to foster invention; vague claims would deter inventors by confronting them with an undue risk of infringement. See United Carbon Co. v. Binney & Smith Co., 317 U.S. 228, 236 (1942) ("statutory requirement of particularity and distinctness in claims is met only when [the claims] clearly distinguish what is claimed from what went before in the art and clearly circumscribe what is foreclosed from future enterprise."); Datamize, LLC v. Plumtree Software, Inc., 417 F.3d 1342 (Fed. Cir. 2005) (quoting United Carbon).

According to the Federal Circuit, a claim is sufficiently definite to satisfy section 112 "[i]f one skilled in the art would understand the bounds of the claim when read in light of the specification." Miles Labs., Inc., v. Shandon, Inc., 997 F.2d 870 (Fed. Cir. 1993). Courts do not demand absolute clarity from valid patents; they only require "that the claims be amenable to construction, however difficult that task may be. If a claim is insolubly ambiguous, and no narrowing construction can properly be adopted, we have held the claim indefinite." Exxon, 265 F.3d at 1375.

The level of precision demanded from a patent claim depends on the patent's subject matter and its relationship to prior art. A patent claim's principal function is to distinguish the claimed invention from prior art. United Carbon, 317 U.S. at 236. This means that when similar prior art does not exist or the subject matter does not allow for great precision, there is some leeway for ambiguity in claim terms. Shatterproof Glass Corp. v. Libbey-Owens Ford Co., 758

F.2d 613, 624 (Fed. Cir. 1985) ("amount of detail required to be included in claims depends on the particular invention and the prior art" and claim language should be "as precise as the subject matter permits"). However, when claim terms serve to distinguish the invention from close prior art, they must be amenable to more definite construction if possible. See Standard Oil Co. v. Am. Cyanamid Co., 774 F.2d 448, 453 (Fed. Cir. 1985); Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1218 (Fed. Cir. 1991). In Amgen the Federal Circuit held invalid a patent claim that disclosed "[h]omogeneous erythropoietin characterized by . . . a specific activity of at least about 160,000 IU per absorbance unit at 280 nanometers." 927 F.2d at 1203; U.S. Patent 4,677,195, claim 4 (filed Jan 11, 1985). The Federal Circuit reasoned that the phrase "characterized by . . . a specific activity of at least about 160,000 IU per absorbance unit" was indefinite because prior art disclosed an urinary erythropoietin product with specific activity of 128,620 IU per absorbence unit. Amgen, 927 F.2d at 1217-18. A person of ordinary skill in the art would find the claim indefinite because it did not "permit one to know what specific activity values below 160,000, if any, might constitute infringement." Id. at 1217.

For any patent approved by the Patent Office, there is a "statutory presumption of validity." Exxon, 265 F.3d at 1375. This means that the burden of proving a patent's invalidity rests with the party that challenges its validity. See 35 U.S.C. § 282. To meet that burden, the party challenging validity bears the burden of proving, by clear and convincing evidence, that the invention fails to meet the requirements of patentability. See Hewlett-Packard Co. v. Bausch & Lomb, 909 F.2d 1464, 1467 (Fed. Cir. 1990). Clear and convincing evidence is evidence that "could place in the ultimate factfinder an abiding conviction that the truth of [the] factual

contentions [is] 'highly probable.'" Colorado v. New Mexico, 467 U.S. 310, 316 (1984).

DISCUSSION

The dispute between the parties focuses on the Arrhenius' equation term in the patent claims. The term serves to define the scope of the patent by disclosing to a potential infringer whether her product trespasses onto the range of heating times and temperatures disclosed by the patent. If a potential infringer is unable to apply the Arrhenius' equation term, she will not be able to determine the scope of Howmedica's invention and will be confronted by an undue risk of infringement. See United Carbon, 317 U.S. at 236. The nature of the subject matter addressed by the Arrhenius' equation claim term, which purports to define an exact minimum time period for heating the polymer at any given temperature, suggests that the Court should require that the term be construable with a relatively high degree of precision.

Moreover, the prosecution history of the '934 Patent demonstrates that the Arrhenius' equation term in the patent claim serves to distinguish Howmedica's invention disclosed by the claims at issue from prior art. Howmedica's initial application discloses an irradiated polymer "heated at a temperature of greater than 25°C to create cross-links between free radicals." (Decl. of Imron T. Aly, July 21, 2006, Ex. 4, Patent App. 09/012,345, dated Jan. 23, 1998, at 20.) The claims in that application contained no further restrictions on the time and temperature combinations that could be used. The patent examiner rejected the proposed claims under 28 U.S.C. 102(b) because prior art anticipated the disclosed invention. The examiner cited Robert M. Streicher's "Investigation on Sterilization and Modification of High Molecular Weight

Polyethylenes by Ionizing Radiation" ("Streicher 1989") which had disclosed annealing ultra-high molecular weight polyethylene "for two hours at temperature from 40 C to 80 C" after irradiation. (Aly Decl. Ex. 5, PTO Office Communication, dated Sept. 4, 1999, at 2-3. See also Aly Decl. Ex. 8, Streicher 1989, at 35.)

To save its patent, Howmedica narrowed its the claimed invention by limiting its claim to avoid prior art. It did this by including the Arrhenius' equation term in its patent:

> In order to distinguish the present embodiment of the invention over Streicher 1989, applicant has amended the claims . . . . Thus, the claims contemplate that the material is . . . annealed to form cross-links between free radicals at any time-temperature equivalency (as determined by Arrhenius' equation) that is at least the same as heating . . . [the] material to 50°C for 144 hours.

(Aly Decl. Ex. 6, Response to Office Action, dated Dec. 9, 1999, at 7.) Since Howmedica expressly resorted to the Arrhenius' equation term to distinguish the invention disclosed by '934 Patent from similar prior art, the term must be susceptible to more definite interpretation than otherwise. See Amgen, 927 F.2d at 1218. Otherwise, the claim would not "clearly distinguish what is claimed from what went before in the art and clearly circumscribe what is foreclosed from future enterprise." United Carbon, 317 U.S. at 236.

To show that the Arrhenius' equation term is not amenable to definite interpretation, defendants initially point to the multiple undefined variables in the equation as set forth in the specification and various statements in the record. They argue that a person of ordinary skill in the art, confronted by the patent claims and specifications, would be unable to apply Arrhenius' equation to determine whether heating the polymer for any given time at a certain temperature is equivalent to heating the polymer for 144 hours at 50°C. That person could not determine from

the patents, defendants argue, whether her product infringes on Howmedica's.

Howmedica responds by setting forth a single method for interpreting the Arrhenius' equation term. This method requires that a person of ordinary skill in the art identify two equivalent time/temperature pairs from the patent. Once she has identified the two equivalent pairs, the person can derive the various unknown terms in Arrhenius' equation as presented in the specification. Then, having filled in the various unknown terms, she can easily calculate the boundaries of the patent. In other words, if a person knows that heating the polymer for 144 hours at 50°C will allow for the same level of cross linking and elimination of free radicals as heating the polymer for X hours at Y°C, then the remaining terms of the equation may be determined. According to Howmedica, a person of ordinary skill in the art could indentify from the patent claims and specifications two equivalent time and temperature pairs, derive the necessary Arrhenius' equation variables, and then apply the resulting equation to determine the period required at a given temperature, and vice versa.

As factual support for its assertion, Howmedica submits two expert declarations. The first is by Dr. William M. Risen, Jr., Ph.D, a Professor of Chemistry at Brown University. (Decl. of William M. Risen, Jr., Aug. 24, 2006.) The second is by Dr. Stephen Li, Ph.D., president of Medical Device Testing and Innovations, LLC. (Decl. of Dr. Stephen Li, Aug. 24, 2006.) Dr. Li received his Ph.D in Chemistry from the University of Southern California in 1977. Defendants' did not contest the experts' qualifications in their papers or at oral argument.

Both Dr. Li and Dr. Risen begin by stating that heating the polymer for 144 hours at 50°C and for 4 hours at 130°C are equivalent time and temperature pairs. Dr. Risen reasons:

NOT FOR PUBLICATION

> In US 6,174,934 B1, the inventors described a type of material obtained, in part, by heating an irradiated ultra-high molecular weight polyethylene under conditions of time and temperature designed to create crosslinks and reduce free radicals. They claim that the post-irradiation heating must be done in a way that is at least equivalent to heating it for 144 hours at 50°C. Thus, this is the minimum heating time specified at 50°C. The minimum heating time at a higher temperature is given as 4 hours at the high end of the range, which leads to a minimum annealing time of 130°C.

(Risen Decl. ¶ 14.) Dr. Li expressly asserts that a person of ordinary skill in the art would interpret the specification and claims to disclose that heating the material for 144 hours at 50°C is equivalent to heating it for 4 hours at 130°C:

> [I]t is my opinion that one of ordinary skill in the art would read the specification of the patents in suit to teach that heating irradiated UHMWPE material at 130 C for 4 hours or heating irradiated UHMWPE material at 50 C for 144 hours would provide UHMWPE with a sufficient number of crosslinks to be in accordance with the invention disclosed in the specifiation of the patents in suit.

(Li Decl. ¶ 27.)

Drs. Lee and Risen then methodically explain how, through a series of calculations, a person of ordinary skill in the art would apply the equation using the two time/temperature pairs. In brief, she would use the "two time/temperature heating combinations" to "calculate the activation energy ▲H to be used in in the Arrhenius equation in order to calculate additional time/temperature heating combinations that are equivalent to heating UHMWPE material at 50 C for 144." (Li Decl. ¶ 30.)

Dr. Li, when deposed in July 2006, confirmed that Howmedica's entire argument that the Arrhenius' equation term is amenable to construction depends on the assumption that heating the polymer for 144 hours at 50°C is equivalent to heating it for 4 hours at 130°C:

> Q. Okay. I take it that the accuracy of any calculations made in that way would depend on you being correct about 130 C at four hours being the equivalent to 50

NOT FOR PUBLICATION

> C at 144 hours, right?
>
> A. They would both have to get you to the same material property or material description that they want you to get to, yes.

(Certification of Jason S. Oliver, Aug. 28, 2006, Ex. D 107:3-9.) Dr. Li's response is in accord with the method by which he and Dr. Risen apply Arrhenius' equation in their declarations. Neither Dr. Li nor Dr. Risen suggest that there exists any method for applying the Arrhenius' equation term that does not depend on identifying two equivalent time/temperature pairs.[4]

Howmedica bases its assumption that 4 hours at 130°C is equivalent to 144 hours at 50°C on a single passage of the '934 Patent's specification:

> In general, the desired elevated temperature is between the room temperature and the melting point of the polymer. For UHMWPE, this temperature range is between about 25°C and about 140°C. However, the preferred annealing temperature range is from about 37°C to about 135°C. The preferred time and temperature is 130°C for 20 hours with the minimum annealing time being about 4 hours (requiring a temperature at the high end of the range).

'934 Patent, 5:57-63. From the evidence it appears that this passage is the sole support for the claim that 4 hours at 130°C is equivalent to 144 hours at 50°C. The Li and Risen Declarations clearly refer to this passage as the basis for indentifying 4 hours at 130°C as one of the pairs. Aside from this passage, Dr. Li and Risen cite no other basis for their assumption that heating the polymer for 4 hours at 130°C is equivalent to heating it for 144 hours at 50°C. Moreover, they

---

[4]In an earlier declaration, submitted in support of Howmedica's claim construction, Dr. Li suggested that the Arrhenius' equation term could be reduced to a rule of thumb. According to this rule, for every 10°C increase in temperature the time required is halved. (Aly Decl. Ex. 36 ¶ 21.) Dr. Li's current testimony contradicts his rule of thumb. As example, in the present declaration Dr. Li claims that if the heating temperature is raised from 120°C to 130°C, the time required decreases from 5.8 hours to 4 hours, not 2.9 hours. (Li Decl. ¶ 34.)

never assert that heating the polymer for 4 hours at 130°C in fact achieves the same level of cross-linking as heating it for 144 hours at 50°C. At oral argument, Howmedica's counsel was also only able to point to this one passage of the specifications when the Court asked him to explain how person of ordinary skill in the art could determine the two equivalent time/temperature pairs.

According to counsel, a person of ordinary skill in the art would interpret "preferred time and temperature is 130°C for 20 hours with the minimum annealing time being about 4 hours (requiring a temperature at the high end of the range)" to mean that the minimum required time is 4 hours at 130°C. But the passage only states that the minimum annealing time is four hours at the "high end of the range," and mentions two ranges: the UHMWPE "temperature range" ("between about 25°C and about 140°C") and the "preferred annealing temperature range" ("from about 37°C to about 135°C").[5] Nowhere in the specification is 130°C described as at "the high end of the range." Neither counsel nor Howmedica's experts can provide any reason for their belief that a person of ordinary skill in the art would pair 4 hours with 130°C, rather than 135°C or 140°C.

The Court is not also not convinced that a person of ordinary skill in the art, even if she determined that the passage identified 4 hours at 130°C as a time/temperature pair, would

---

[5]Dr. Li, in his deposition testimony, agreed with the statement that "140 degrees C is the high end of the range disclosed in the patent." (Supplemental Certification of Jason S. Oliver, Sept. 11, 2006, Ex. H 96:23-97:02.) He also agreed that it was possible that the temperature range in the '308 Patent would potentially "go up to, say, 200 degrees C." Id. at 98:11-99:06. It is quite unclear to the Court how Dr. Li can now assert in his declaration that a person of ordinary skill in the art would interpret "a temperature at the high end of the range" to mean 130°C.

NOT FOR PUBLICATION

believe that pair to be equivalent to 144 hours at 50°C. First, the specification passage that describes heating the polymer for "130°C for 20 hours with the minimum annealing time being about 4 hours" concerns pre-irradiation heating. In contrast, "50°C for 144 hours" in the patent claims describes post-irradiation heating. Howmedica, Dr. Risen, and Dr. Li do not explain or state that the pre-irradiation heating times are relevant or equivalent to the post irradiation heating time. In other words, there is no argument made that heating the polymer for 144 hours at 50°C after it has been irradiated is equivalent to heating it for 4 hours at 130°C before irradiation.

Second, 144 hours (at 50°C) is a preferable heating time, but 4 hours (at 130°C, 135°C, or 140°C) is a minimum time. The specification expressly only describes 144 hours at 50°C as a preferable time, never as a minimum time: "[i]n general, the implant is heated for at least 48 hours at a temperature of about 37 to 70°C and preferably for 144 hours at 50°C." '934 Patent, 4:44-46. Similarly, the specification also identifies 20 hours as the preferred time at 130°C: the "preferred time and temperature is 130°C for 20 hours." '934 Patent, 5:60-61. In contrast, that passage describes 4 hours as the "minimum annealing time." '934 Patent, 5:61-62.

In short, neither Howmedica nor its experts provide any basis for assuming that 4 hours at 130°C is equivalent to 144 hours at 50°C. Defendants have demonstrated that the passage of the specification that Howmedica relied upon is ambiguous, is irrelevant to post-irradiation heating, and even contradicts Howmedica's experts' position. Defendants have proven, by the defects in Howmedica's evidence and by the statements of Howmedica's own experts, that it is highly probable that a person of ordinary skill in the art would be unable to determine that 4 hours at

130°C is equivalent to 144 hours at 50°C.

Contrary to Howmedica's assertions, the specification discloses at least three time/temperature pairs that could be equivalent to 144 hours at 50°C, the first being the most plausible: (1) 20 hours at 130°C, (2) 4 hours at 140°C, and (3) 4 hours at 135°C. If a person of ordinary skill in the art assumes that any one of these three alternatives is equivalent to 144 hours at 50°C, she will arrive at an entirely different interpretation of the scope of Howmedica's patents from that proposed by Howmedica's experts. Because a person of ordinary skill in the art would not be able to discern whether a competitor's similar product actually infringes on Howmedica's patents, the Court finds the claim indefinite.

CONCLUSION

Defendants have proven by clear and convincing evidence that the Arrhenius' equation terms in the '934, '814, and '308 Patents are insolubly ambiguous. Accordingly, the Court finds the '934, '814, and '308 patent claims at issue invalid and grants summary judgment to defendants on this ground. Since the Court has found that the '934, '814, and '308 Patent claims at issue are indefinite, the Court will not consider the defendants' motion for summary judgment on non-infringement. An appropriate order will issue.

June 13, 2007

s/ William H. Walls
United States Senior District Judge